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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/600,052 | 06/20/2003 | Aaron Kelly | 31132.129 | 6026 |
| 46333 | 7590 | 05/19/2008 | | |
| HAYNES AND BOONE, LLP | | | EXAMINER | |
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| Suite 3100 | | | | |
| Dallas, TX 75202 | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/19/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/600,052

Applicant(s)

KELLY ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 26-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19, 26-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 101-103,106-110,112-113 of copending Application No. 09/924,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 1-19, 26-34 of the application and claims 101-103,106-110,112-113 of the copending application lies in the fact that the copending application claims include many more elements and are thus more specific. Thus, the invention of claims 101-103,106-110,112-113 of the copending application is in effect a "species" of the "generic" invention of claims 1-19, 26-34. It has been held that the generic invention is "anticipated" by the "species" See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1-19, 26-34 of the application are anticipated by claims 101-103,106-

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110,112-113 of the copending application, they are not patentably distinct from claims 101-103,106-110,112-113.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2-7,10-19, 26-29, 32, 33 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Pope et al (6,290,726) in view of Larsen et al. (5,782,832).

Pope et al disclose a body member (2055) for use with a shell (2051, 2052) to form an implantable endoprosthesis, the body member comprising a first component having an articular surface (2053a) for articulated movement with the shell (2051a) the first component formed from a wear resistant first material, and a second component (2053c), wherein the body member is adapted to articulate with respect to the shell such that one or more surface of the shell come into contact with the articular surface of the first component, as best seen in FIG. 2Z, a second component (2053c), wherein the second component is disposed between the first component (2053a) and a third component (2053b) also formed from the first material (wear resistant material) The third component having an articular surface for articulated movement with the shell;

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wherein the body member is adapted to articulate with respect to the shell such that one or more surfaces of the shell come in contact with the articular surfaces of the first and third components during articulation, as best seen in FIG. 2z, as set forth in column 18, lines 47-67, column 19, lines 1-3. A first portion (2053a) configured to articulate with a first surface of the shell structure, the first portion formed from a first wear resistant material; a second portion (2053b) configured to articulate with the second surface of the shell structure, the second portion formed from a second wear-resistant material; and a third portion (2053c) positioned at least partially between the first and second portions to avoid contact with the shell structure.

Although Pope et al teach that the second component could be made of more than one material, such as polymer material, it is noted that Pope et al did not teach of a second component made of a resilient material; as claimed by applicant. However, in similar art, Larsen et al evidences the use of a second component made of resilient material to provide a cushion between first and second supports or shells.

Therefore, given the teaching of Larsen et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pope; as taught by Larsen et al., to provide a cushion between first and second supports or shells.

With respect to claims 17-19, 27-29, 32, 33, Pope et al. disclose all the limitations, as set forth in column 18, lines 47-67, column 19, lines 1-3; and as set forth in column 8, lines 1-67, and as best seen in FIGS. 19, 20, 25, 26.

With respect to claims 3-16, it is noted that Pope et al teach all the limitations except for the material being one or more metal and the metal is an alloy and the alloy is cobalt-chrome alloy, and the material is ceramic herein the ceramic is alumina or zirconia and a molecular weight ranging from about 5.0×10^5 grams/mol to about 6.0×10^6 grams/mol; polyethylene having modulus of elasticity ranging from about 0.7 to about 3.0 Gpa; A polyethylene cross-linked to an extent ranging between about 0 to about 50% as measure by a swell ratio; polymer comprising (PEEK) and the second material comprises polymer having durometer ranging from about 75A to about 65D; as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art to use any known or preferred material; since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. As to the ranges and percentages as claimed by applicant, It would have been obvious to one having ordinary skill in the art to reach an optimum range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 30, 31, are rejected under 35 U.S.C. 103(a) as being unpatentable over Pope et al. (6,290,726) in view of Larsen et al (5,782,832) in view of Buttner-Janz et al. (5,401,269).

With respect to claims 30, 31, it is noted that the above combination of references discloses all the limitations, except for an opening adapted to receive a first

projection and second projection of the shell; as claimed by applicant. However, in a similar art, Buttner-Janz et al evidence the use of a core having an opening adapted to receive a projection of the shell to limit the rotational movement and the bending movement of the prosthesis.

Therefore, given the teaching of Buttner-Janz et al, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the device of Pope/Larsen et al, as taught by Butter-Janz et al to limit the rotational movement and the bending movement of the prosthesis.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pope et al. (6,290,726) in view of Larsen et al. (5,782,832) in view of Suddaby (6,395,034).

With respect to claim 34, it is noted that the above combination of references teaches all the limitations, except for a recess in the first portion and a projection in the second portion; as claimed by applicant. However, in a similar art, Suddaby evidences the use of an intervertebral disc prosthesis with a recess in the first portion and a projection in the second portion adapted to engage the recess in the first portion allowing the first portion and the second portion to move away and toward from each other.

Therefore, given the teaching of Suddaby, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pope/Larsen et al, as taught by Suddaby, to allow the first portion and the second portion to move away and toward each other.

Response to Amendment

Applicant's arguments filed 2/20/08 have been fully considered but they are not persuasive. Applicant stated that using the resilient material such as a synthetic rubber or elastomeric material in the device of Pope would destroy the purpose or function of the device of Pope. The examiner begs to differ. Pope first concern is to minimize wear and tear and a decreased coefficient of friction, therefore having maximum life of the replaced joint. In column 11, lines 13-63, Pope discloses that the substrate could be a super-hard material, a corrosion-resistant metal, ceramic or polymer material. Since the substrate could be a polymer, and only the surface needs to be a polycrystalline diamond, replacing the polymeric material of Pope with the elastomeric material of Larsen et al would have been obvious to one having ordinary skill in the art. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. In this present case, the elastomeric material of Larsen would be covered with the polycrystalline diamond material as taught by Pope, thereby still providing an implant having increased wear resistant and a decreased coefficient of friction.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/
Primary Examiner, Art Unit 3733
May 16, 2008